Message

From: Vulimiri, Suryanarayana [Vulimiri.Sury@epa.gov]
Sent: 7/10/2013 12:23:51 PM
To: Kraft, Andrew [Kraft.Andrew@epa.gov]; Adams, Lynn [Adams.Lynn@epa.gov]; Guyton, Kate [Guyton.Kate@epa.gov]
CC: Sonawane, Bob [Sonawane.Bob@epa.gov]; Nath, Raghu [Nath.Raghu@epa.gov]; Glenn, Barbara [Glenn.Barbara@epa.gov]; Gibbons, Catherine [Gibbons.Catherine@epa.gov]; Keshava, Nagalakshmi [Keshava.Nagu@epa.gov]
Subject: RE: AGENDA AND ATTACHMENT ADDED: Discuss potential need for review of mutagenicity studies in formaldehyde Call In: [1-866-299-3188 x2023439797]
Attachments: FA - GeneTox 06132013_with HERO links.docx

Hi Andrew,
I have a clean version of the Genetox section. See the attachment.

FA - GeneTox 06132013_with ...

Sury

-----Original Appointment-----
From: Kraft, Andrew
Sent: Wednesday, July 10, 2013 8:13 AM
To: Vulimiri, Suryanarayana; Adams, Lynn; Guyton, Kate
Cc: Sonawane, Bob; Nath, Raghu; Glenn, Barbara; Gibbons, Catherine; Keshava, Nagalakshmi
Subject: AGENDA AND ATTACHMENT ADDED: Discuss potential need for review of mutagenicity studies in formaldehyde Call In: [1-866-299-3188 x2023439797]
When: Wednesday, July 10, 2013 10:30 AM-12:00 PM (GMT-05:00) Eastern Time (US & Canada).
Where: DCRoomPYN7771-North/ORD-NCEA-DC

Agenda (discussion format):

Our goal is to try and answer the following questions. It may be a bit tight in one hour, so let's at least try to get through #1-3 (the whip will be cracked on sidebar conversations)

1) In general, for current assessments, how are studies being evaluated for genotoxicity/ mutagenicity studies? Is it systematic? (Question geared towards Catherine and Nagu)
2) Specifically for formaldehyde, is it necessary to evaluate studies (or specific aspects of studies) for their level of "informativeness"? (Group discussion, Sury and Barbara/ Andrew to provide context)
3) Given the formaldehyde database (Sury can elaborate), are there **types** of studies that are more informative or influential, from a evidence of mutagenicity/ evidence of systemic genotoxicity standpoint? For these studies, what are the most important experimental features that should be critically and systematically evaluated? (Gene-tox expert discussion)
4) For the types of studies identified for formaldehyde, can we begin to develop a step-wise approach (e.g., for certain study types, can we get by with evaluating nothing; for others, just the level of relevance of the test article; and for others, a full evaluation)? It is notable that some studies may be used somewhat differently in the genotoxicity section versus the MOA sections. (Group discussion in the context of a short timeline to release—study examples may be provided by Barbara/ Andrew [time permitting] or may be described by Sury/ Lynn)
5) What are the agreed-upon next steps and responsibilities?

Relevant sections of the formaldehyde review for this discussion include the genotox section (attached), as well as the cancer MOA sections (Lynn Adams is the author and should be available to provide context)... [Note: the repercussions

of the mutagen./ genetox conclusions extend well beyond these sections, to the cancer hazard descriptors and dose-response analyses, infinity and beyond]

<< File: genotoxicity 070913 for discussion.docx >>